K081556

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5 510(k) Summary

This 510(k) summary is submitted as part of the PreMarket Notification in accordance with the requirements of SMDA 1990, 21 CFR 807.87(h), and 21 CFR 807.92.

1. Date Prepared	December 16, 2008
2. 510(k) Submitter	Confirma, Inc. 11040 Main Street, Suite 100 Bellevue, WA 98004 Phone: 425-691-1400 Fax: 425-691-1599
3. 510(k) Contact Person	Brent Lewis, Director Regulatory Affairs and Quality Assurance Email: blewis@confirma.com Phone: 206-455-5398 Fax: 425-691-1599
4. Device Common Name	Image Processing System
5. Device Trade Name	CADstream Version 5
6. Classification Regulation	21 CFR 892.2050
7. Class	2
8. Panel	Radiology Panel
9. Product Code	LLZ

10. Comparison with Legally Marketed Devices

As with the predicate devices listed in Table 1, CADstream version 5 is indicated for use in the visualization, analysis, reporting, interventional planning, and improved workflow efficiency of magnetic resonance imaging (MRI) studies and supports the evaluation of dynamic MR data acquired during contrast administration. All these devices are intended to provide information that may be useful in screening or diagnosis.

Table 1: Predicate Devices

Manufacturer	Product	Cleared 510(k)	Product Code	Classification
Confirma	CADstream 5	Pending	LLZ	2
	CADstream 4	K043216	LLZ	2
	CADstream 2	K031779	LLZ	2
Invivo	DynaCAD 1.0	K041286	LLZ	2
CADsciences	3TP	K031350, K050862	LLZ	2
GE Medical	AW & Functool	K960265	LLZ	2
Clario	Z3D Contrast Acuity	K080196	LLZ	2

Table 2 presents a detailed comparison of features in CADstream version 5 to the predicate devices.

Table 2: Predicate Device Feature Comparison

CADstream 5 Features	Predicate Devices				
	CADstream 2 & 4	DynaCAD 1.0	AW & Functool	3TP	Z3D
General Body MR Functions					
Standard image viewing tools	X	X	X	X	X
View/play clips from ultrasound images	X	0	0	0	0
MIPs	X	X	0	X	X
Reformats	X	X	0	0	X
Registration	X	X	0	X	X
Subtraction series	X	X	0	X	X
Coil inhomogeneity correction		X	0	0	0
View 3D volume rendering	X	X	X	0	X
Kinetic curves	X	X	X	X	X
Parametric image maps	X	X	X	X	X
Portfolio of user-selected findings	X	X	X	X	X
DICOM import/export and query/retrieve	X	X	X	0	0
User-Customizable Reporting	X	X	0	X	X
Breast Specific: Module Features					
Reporting for Breast MR Studies	X	X	0	X	0
View/invert mammography images	X	X	0	0	0
View/edit finding volume	X	X	0	X	0
View/edit finding location	X	X	0	X	0
View/edit finding size	X	X	0	X	0
View/edit kinetic curve with highest uptake	X	X	0	X	0
View images and findings from two studies from same patient	X	X	0	X	0
Interventional planning	X	X	0	0	0

Key

X Substantially equivalent feature cleared in predicate device.

0 Not known from literature.

11. Device Description

CADstream is an image processing system designed to assist in the visualization, analysis, and reporting of magnetic resonance imaging

(MRI) studies. CADstream also is intended to provide workflow efficiency and interventional planning tools.

CADstream receives DICOM magnetic resonance images from a PACS or directly from the MRI scanner. As they are received, CADstream processes and displays the results on the CADstream server or a client personal computer.

Available features support:

- Visualization (standard image viewing tools, MIPs, and reformats)
- Analysis (registration, subtractions, coil inhomogeneity correction, kinetic curves, parametric image maps, and 3D volume rendering)
- Reporting of user-selected findings and assessment
- Interventional planning
- Workflow efficiency
- Communication and storage (DICOM import/export, query/retrieve, and study storage)

The CADstream system consists of proprietary software developed by Confirma installed on an off-the-shelf computer.

12. Indications for Use

CADstream is intended to be used in the visualization, analysis, and reporting of magnetic resonance imaging (MRI) studies. CADstream supports evaluation of dynamic MR data acquired during contrast administration. CADstream performs other user selected processing functions (such as image registration, subtractions, measurements, 3D renderings, and reformats).

CADstream also includes user-configurable features for reporting on findings in breast or general MRI studies. Additionally, CADstream assists users in planning MRI guided interventional procedures.

When interpreted by a skilled physician, this device provides information that may be used for screening, diagnosis, and interventional planning. Patient management decisions should not be made based solely on the results of CADstream.

CADstream may also be used as an image viewer of multi-modality, digital images, including ultrasound and mammography. CADstream is not intended for primary interpretation of digital mammography images.

13. Performance Testing

CADstream version 5 has successfully undergone extensive verification testing to verify the device meets input requirements. Bench validation testing was also performed to demonstrate the product modifications from version 4 resulted in a substantially equivalent product and did not raise any new safety or effectiveness concerns. Additionally, the completed clinical validation testing demonstrates the device conforms to user needs and intended uses per 21CFR820.30(g).

14. Conclusion

CADstream Version 5 provides features to integrate radiology department workflow by facilitating the visualization, analysis, and reporting of MR images. The potential hazards have been studied and controlled as part of the product development process, including risk analysis and design considerations. The successful completion of verification and validation testing has demonstrated conformance to design controls, user needs, and intended use, and that the device is safe and effective.

Based on the information supplied in this 510(k), we conclude that the subject device is safe, effective, and substantially equivalent to the predicate devices.

6 Truthful and Accurate Statement

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

[As required by 21 CFR 807.87(k)]

I certify that, in my capacity as Acting Director of Regulatory Affairs at Confirma, Inc., I believe to the best of my knowledge, that all data and information submitted in this 510(k) PreMarket Notification are truthful and accurate and that no material fact has been omitted.

Brent Lewis
Acting Director, Regulatory Affairs
Confirma, Inc.

02 Jun 2008
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 2 2009

Mr. Brent Lewis
Director, Regulatory Affairs and Quality Assurance
Confirma, Incorporated
11040 Main Street, Suite 100
BELLEVUE WA 98004

Re: K081556
Trade/Device Name: CADstream® Version 5
Regulation Number: 21 CFR §892.2050
Regulation Name: Picture archiving and communications systems
Regulatory Class: II
Product Code: LLZ
Dated: December 23, 2008
Received: December 23, 2008

Dear Mr. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4 Indication(s) for Use Statement

510(k) Number: K081556

Device Name: CADstream® Version 5

Indications for Use:

CADstream is intended to be used in the visualization, analysis, and reporting of magnetic resonance imaging (MRI) studies. CADstream supports evaluation of dynamic MR data acquired during contrast administration. CADstream performs other user selected processing functions (such as image registration, subtractions, measurements, 3D renderings, and reformats).

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Prescription Use X (Part 21 CFR 801 Subpart D) ~~AND/OR~~ Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K081556